

PROTOCOL TITLE: *Vaginal Electrical Stimulation for Postpartum neuromuscular Recovery (VESPR)*

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1.0 Objectives

1.1 Primary Aim: *To compare fecal incontinence (FI) symptom severity at 3 months postpartum using a validated questionnaire (Fecal Incontinence Severity Index (FISI)) in women who sustain an OASIS (Obstetric Anal Sphincter Injuries) with their first delivery and begin immediate vaginal electrical stimulation compared with those who receive sham therapy*

1.2 Secondary Aims:

- To compare neuromuscular function in these two groups using pudendal nerve terminal motor latencies (which measure neural function) and anal manometry (which measures muscle strength).*
- To compare pelvic floor muscle strength in these two groups using a validated instrumented speculum that detects force in Newtons.*
- To compare stress urinary incontinence (SUI) and overall urinary incontinence (UI) symptoms in these two groups using validated questionnaires (UDI-6, PFIQ-7)*
- To determine the relationship between levator ani muscle defects and anal sphincter muscle defects and responses to vaginal*

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electrical stimulation in these two groups using endoanal and endovaginal ultrasound which allow visualization of muscle morphology and measurements of bloodflow.

1.3 Hypothesis: *We hypothesize that vaginal electrical stimulation given immediately after delivery and then regularly in the postpartum period will augment neuromuscular recovery, resulting in improved pelvic floor symptoms and function. Our previous work funded by the Evergreen Invitational Grants Initiative¹⁷ has shown high rates of both fecal and urinary symptoms in women who sustained 3rd or 4th degree obstetric anal sphincter injuries (OASIS) (i.e. severe tears) at the time of their first delivery. Given the high rates of pelvic floor symptoms and muscular dysfunction in this group, they represent an ideal group to study.*

2.0 Background

2.1 *Pregnancy and vaginal childbirth are prevailing risk factors for pelvic floor disorders (PFD), including fecal and urinary incontinence, during the reproductive years.¹⁻³ Within 3-months of vaginal delivery, approximately one third of women report symptoms of a PFD. The onset of symptoms during pregnancy is strongly predictive of postpartum symptoms; even when symptoms resolve immediately postpartum, women remain at higher risk for return of symptoms later in life. It is thought that temporary physiologic or neuromuscular changes during pregnancy may predispose certain women to symptomatic PFD later in life. Specific neuromuscular changes (histologic and electromyographic) consistent with neuromuscular injury to pelvic floor muscles immediately after childbirth were first described over 20 years ago, establishing neuromuscular injury as an essential component of PFD after vaginal delivery.⁴⁻⁷ More recently, investigators demonstrated that clear anatomic disruptions or defects in the levator ani muscles after delivery are also associated with the development of PFD.^{8,9} Studies have shown that neural recovery after vaginal delivery mirrors pelvic floor symptom improvement; electrodiagnostic findings and stress urinary incontinence (SUI) symptoms improve simultaneously in the first 3-6 months after delivery.¹⁰ Despite this, however, the risk of SUI symptoms 5-years after vaginal delivery has been shown to be 4.6 times higher (95%CI 1.8-11.8) in women who reported SUI in the first 3-months after delivery. In fact, 42% of women with resolution of SUI symptoms in the first 3-months postpartum reported recurrent SUI symptoms 5-years later, suggesting incomplete neuromuscular recovery.^{10, 11}*

Other medical fields routinely employ neuro-regenerative techniques to improve neuromuscular recovery after peripheral nerve injury. In the orthopedic literature, electrical stimulation after surgery and strenuous exercise can facilitate neuromuscular recovery and improve outcomes.^{12, 13} One recent study applied electrical stimulation for only 1 hour to the medial nerve after carpal

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tunnel release surgery and demonstrated accelerated and completely restored muscle innervation at 6-months compared to patients who did not receive ES of the median nerve.^{15, 16} Electrical stimulation (ES) depolarizes the actual peripheral neurons and subsequently elicits muscle contractions, inducing physiologic changes that remain after the actual stimulation, facilitating plastic changes during recovery and leading to improvement of voluntary functions. Increasing data suggest when administered appropriately, electrical stimulation results in neuroplastic changes, including increased nerve fiber density. Application of this technology of electrical stimulation to women after childbirth may result in profound neuromuscular recovery, thus minimizing rates of pelvic floor disorders in this population.

3.0 Inclusion and Exclusion Criteria

3.1 *Women who sustain an OASIS during their first delivery will be approached for study participation in the hospital within 12-48 hours of delivery or at their first clinic visit (within 1 week of delivery) to the peripartum evaluation and assessment of the pelvic floor after delivery (PEAPOD) clinic. The Northwestern Enterprise Data Warehouse (EDW) will be used to identify women who have sustained an OASIS in the past 12-hours, and checked between 7am to 7pm.*

3.2 Inclusion Criteria:

- *Women who sustain OASIS during first vaginal delivery*
- *Between age of 18-50 years of age*
- *English speaking and reading*

3.3 Exclusion Criteria:

- *implanted electrical device*
- *neurological disorder*
- *inflammatory bowel disease*
- *wound breakdown and infection*
- *anticipated geographic relocation*
- *mediolateral episiotomy*

3.4 *The following special populations will **not** be included in the study:*

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

4.0 Study-Wide Number of Subjects

4.1 *100 women will be recruited to this study (50 in each arm).*

5.0 Study Timelines

5.1 *Subjects will be approached 12-48 hours of their delivery. If they*

Overall Timeline	Month 1-5	Month 6-10	Month 11-15	Month 16-18
Subject Recruitment/Initial Evaluation	X	X		
Electrical stimulation protocol	X	X	X	
13 wk postpartum evaluation		X	X	
Data Analysis and Manuscript Preparation			X	X

consent to the study, they will remain in the study for 13 weeks after starting therapy

5.2 *It is anticipated that it will take approximately 10 months to enroll all study subjects.*

5.3 *It is estimated that it will take 18 months to complete this study, including the data analysis and manuscript preparation.*

6.0 Study Endpoints

6.1 *The primary study endpoint is 13 weeks, when the subject undergoes a clinical assessment and completes validated questionnaires.*

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7.0 Involved

Subject Timeline	12-48 hr	1 wk	5wk	10wk	13wk
Recruitment	X	X			X
Questionnaires		X	X	X	X
Instrumented speculum exam of pelvic floor muscle strength		X			X
Neuromuscular testing		X			X
Endoanal and endovaginal ultrasound		X (endovaginal only)			X
Device interrogation			X	X	X

Procedures

7.1 This will be a double-blinded, randomized clinical trial of vaginal electrical stimulation versus sham stimulation to determine the effect of vaginal electrical stimulation on pelvic floor symptoms and neuromuscular recovery in women with OASIS.

7.2 Research Procedures:

- **Randomization:** Enrolled participants will be randomized into one of two intervention groups (vaginal electrical stimulation or sham stimulation) with equal probability. A randomly permuted block randomization schema will be generated and maintained using the REDCAPs database. Treatment allocation will be done by a separate investigator, a nurse practitioner.
- **Masking:** Patients and study physicians will be masked to treatment allocation until obtaining primary outcome at 13 weeks after delivery. The research coordinator will be responsible for randomizing participants and providing a functioning or sham electrical stimulation device to the patient at their 1 week postpartum visit. Interrogation of stimulation devices will be performed by the research coordinator. All postpartum evaluations, symptom, and quality of life data will be obtained by a trained examiner masked to the intervention. This will reduce bias by maintaining masking in data collection of outcome measures. All research staff will be trained and certified to perform data collection procedures. Baseline data will be obtained within 1-week of delivery, and the primary outcome will be evaluated within 13 weeks of delivery with a three-week window on either side.
- **1 week clinical assessment:** All women will undergo standardized assessment within 1 week of delivery, including demographic information (age, race/ethnicity, BMI, etc), obstetrical and medical data (medical/surgical history, type of

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delivery, duration of second stage, anesthesia utilized, antibiotic use, degree of tear, suture used for repair, birth weight, and fetal head position). Women will also complete all validated questionnaires and undergo clinical assessment including perineal exam, pelvic floor muscle strength with the instrumented speculum designed by the University of Michigan (see supplemental information), pelvic and perineal ultrasound to assess levator ani muscles and anal sphincter muscles morphology and vascular flow, and neurophysiologic testing including pudendal nerve latency and anal manometry. If women are found to have evidence of infection or wound breakdown, they will be excluded from the study. Their primary obstetrician will be notified, but we will assume responsibility for treating the breakdown/infection. Our peripartum evaluation and assessment of the pelvic floor after delivery (PEAPOD) clinic (run by Dr. Lewicky-Gaupp) is where most obstetricians refer patients with wound breakdown/infection. Thus, we routinely care for patients with these complications after delivery.

- ***Treatment protocol:*** *All of the patients will be given detailed instructions about the use of the device. Specifically, both the electrical stimulation and sham group will be instructed on how to insert the device into the vagina (depth of ~4inches) and turn the device on/off. The 'on' light will function in both groups. The electrical stimulation group will receive stimulation when the device is powered on. In the sham group, the light will turn on but no electrical stimulation will be delivered.*
- ***5 and 10 week clinical assessment:*** *Interrogation of the stimulator device as well as the sham device will be performed to ensure compliance and adjust amplitude settings as needed. At these time points, patient will fill out 2 questionnaires (PFDI-20 and FIS).*
- ***13 week clinical assessment:*** *Patients will complete validated questionnaires and undergo same clinical assessment as was performed during week 1.*

7.3 *Procedure safety and source records:*

- *The device that will be used to provide vaginal electrical stimulation, In Control Medical's Apex M Device, is available over the counter (4/9/2015 K150183) and designed specifically to provide stimulation to the pelvic floor muscles and*

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surrounding structures to improve strength and support. It is safe and there should be minimal to no discomfort with use. The current is set by the patient and physician together to minimize any discomfort and maximize comfort level.

- The source records to collect demographic data and medical/surgical history from the patients will include the EDW as well as EPIC medical records. Other source records include questionnaires that will be administered via RedCAP, a secure, Northwestern approved, electronic data capture system.*

7.4 *The data that will be collected includes:*

- Demographic information (Age, race/ethnicity, BMI)*
- Obstetrical and Medical Data (Medical/surgical history, type of delivery, duration of second stage of pregnancy, anesthesia utilized, antibiotic use, degree of tear, suture used for repair, birth weight, fetal head position).*
- Clinical exam findings (Perineal exam results, pelvic floor muscle strength, pelvic and perineal ultrasound results, neurophysiologic testing results, anal manometry results).*
- Questionnaire data from validated questionnaires (PFDI-20, PFIQ-7, FISI, PISQ-IR, SUS, BSS).*

8.0 Data and Specimen Banking

8.1 *All data will be stored on the secure RedCAP server. The data will only be stored there during the duration of the study, including during the period of data analysis and manuscript preparation. Data will be destroyed 2 years following project completion.*

8.2 *Data to be stored for each subject can be found in section 7.4.*

8.3 *Only the PI and study staff at Northwestern will have access to the data.*

9.0 Data and Specimen Management

9.1 Statistical Analysis: *SPSS statistical software will be used for data management and analysis. Histograms will be used to assess data for normality and where possible any not normally distribute data will be log transformed to allow for parametric statistical test if needed. However, nonparametric tests will be used when appropriate. Continuous data will be compared between study groups using independent t-test or Mann-Whitney U Test. Chi-squared test will be used to compare nominal variables. Repeated measures will be analyzed using paired t-tests, Wilcoxon signed rank test and ANOVA as appropriate.*

9.2 Sample Size Determination:

For the primary outcome for the study, anal incontinence symptom severity at 13 weeks postpartum as measured by total FISI scores, we determined that 42 women (21 in each group) were needed to show a 4-point difference in symptom severity on the FISI questionnaire (MCID of the FISI) between treatment groups with 90% power and a significance level of .05. However, to allow us to explore secondary outcomes like the proportion of women with reduction in FI symptoms, flatal incontinence, the relationship between levator muscle defects and FI symptoms after electrical stimulation and stress incontinence we planned to recruit 100 women. This is based on the following: In a cohort of women at our institution with OASIS after their first vaginal delivery, 55% reported fecal incontinence symptoms 3-months after delivery. We hypothesize that vaginal electrical stimulation will enhance neuromuscular recovery and decrease symptoms of FI by 15% in the first 3 months after delivery. This secondary aim would require that we recruit 40 patients in each group to show a 15% decrease in FI symptoms (from 55% to 40%) with 80% power at a 0.5 significance level. This sample size would also allow us to evaluate flatal incontinence (which has an 82% incidence in our population), the relationship between levator muscle defects and FI symptoms after electrical stimulation, as well as stress incontinence (as 31% of women will have these symptoms immediately after delivery and 17% will have them at 3-months). Assuming a 25% dropout rate, we will ultimately recruit 100 women (50 in each arm) to be able to assess the primary and all secondary outcomes.

9.3 Steps to Maintain Confidentiality: *Data will be collected at Northwestern Medicine. All study data will be recorded on Case Report Forms by research coordinator and securely maintained in a locked cabinet that only the study coordinator has access to. CRFs will be derived from source documentation and/or participant selfreport. Data will be entered by the research coordinator at Northwestern into a RedCAP database that will be stored on a secure sever. Only study staff will have passwords to access the project data on RedCAP.*

9.4 *The data that is banked locally will be entered into an electronic data capture website. All users of REDCap need an institutional username and password to log in and to enter data. Research personnel, including study staff as well as study doctors will be able to collect and have access to subject data.*

10.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects.

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10.1 Data Safety Monitoring Plan:

- *Adverse events associated with use of the electrical stimulation device will be recorded (wound breakdown, wound infection, pain, urinary tract infection). Adverse events will be recorded at each follow up visit on Case Report Forms and subsequently will be added in to RedCAP electronic data capture system. The PI will be notified of any adverse events, which will be resolved with the patient.*
- *The use of the electrical stimulation device is not greater than the minimal risk to subjects,*

11.0 Withdrawal of Subjects*

Subjects may withdraw from the trial at any point.

12.0 Risks to Subjects*

12.1 Risks associated with the project are minimal. Tolerance of the electrical stimulation device has been clearly demonstrated in patients with few side effects and excellent usability scores reported amongst users. Potential risks include discomfort, vaginal irritation, wound breakdown, wound infection, pain, urinary tract infection.

12.2 Risks from the assessment tools include mild discomfort with insertion of the vaginal speculum, ultrasound probe, anal manometry probe. This should be mild discomfort comparable to that associated with a pelvic examination. The pudendal nerve testing includes a tingling sensation that lasts seconds and may be uncomfortable but is not painful.

12.3 Another risk to subjects is that we will be collecting their personal health information in a database. All of the data will be kept confidential and will be stored on password protected, secure servers, or in locked cabinet files that only study staff on the project have access to. Personal health information will be stored on files that are separate from the subject's name, all health information will be coded. Coded list will be kept on secure, password protected file.

13.0 Potential Benefits to Subjects

13.1 It is hypothesized that women who are randomized to the electrical stimulation group may have fewer symptoms of fecal incontinence/ urinary incontinence and greater pelvic floor strength than those receiving the sham stimulation and greater improvement in pelvic floor and neuromuscular strength and function.

14.0 Sharing of Results with Subjects

14.1 Results will not be shared with the patient specifically. At the end of the trial, patients will know which arm they were randomized to. Results of the trial will be published in the medical literature and made publically available.

15.0 Setting

15.1 Potential subjects will be identified and recruited by physicians and the study coordinator within the division of Female Pelvic Medicine & Reconstructive Surgery at Northwestern Medical HealthCare corporation. Subjects will be identified through the EDW from 7am to 7pm by study coordinator and team members. Patients that are eligible for the study will then be approached within Prentice Women's Hospital and asked if they would like to participate in the study. Clinical assessments and follow up research visits will be conducted in Northwestern Medical Group's outpatient clinic, the Integrated Pelvic Health Program (IPHP).

16.0 Resources Available

16.1 The faculty and staff that will be involved in this research are highly qualified. The Principle Investigator, Dr. Christina Lewicky-Gaupp, is an Assistant Professor of Female Pelvic Medicine and Reconstructive Surgery and is the director of the PEAPOD clinic. She has served as primary investigator on many studies, including studies with this same patient population. The other study physicians have also completed their fellowships in Female Pelvic Medicine & Reconstructive surgery and are both involved in numerous research studies and serve as reviewers for several scientific journals. The nurse practitioner on staff at the IPHP has worked on several other protocols during her time at Northwestern. The study coordinator on staff has over 3 years of research experience and 1 year of experience working in clinical trials and consenting patients.

16.2 At Northwestern Prentice Women's Hospital alone, nearly 400 women per year suffer from severe lacerations (OASIS). Around the world, rates of OASIS are rising.¹⁸ In women with OASIS, more than 50% will suffer from fecal or urinary incontinence. Problems of incontinence occur not only postpartum, but also often continue to impact women throughout their lives. Thus, an intervention targeting this large cohort of women would (1) have generalizability to women around the world and (2) have a long lasting impact. Our previous work has demonstrated the ability to successfully recruit subjects from Prentice Women's Hospital. Furthermore, the large volume of deliveries and severe lacerations at this institution make recruitment of eighty patients feasible in the project's timeframe

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16.3 *The Integrated Pelvic Health Program, affiliated with Northwestern Memorial Hospital, helps individuals with pelvic floor disorders. It is the only program in the Chicago area that brings together a multispecialty approach to pelvic floor disorders in one location. Our dedicated team of physicians, nurses, and physical therapists are committed to restoring the quality of life for people with such disorders. Both the physicians and the facilities offer state-of-the-art resources to ensure the highest quality evaluation, medical and surgical care to women with incontinence and prolapsed. Our physicians are national leaders in minimally invasive pelvic reconstructive surgery and sacral nerve stimulation for urinary and fecal incontinence.*

16.4 *All study staff members are in possession of the protocol and the protocol has been reviewed by all of the study members during a research conference. Research procedures have been made clear and were outlined by the study coordinator and Principle Investigator.*

17.0 Recruitment Methods

17.1 *Subjects will be recruited from Prentice Women's Hospital and the the peripartum evaluation and assessment of the pelvic floor after delivery (PEAPOD). They will be identified using Northwestern's EDW, which will be monitored between the hours of 7AM-7PM or during from their clinic visit to PEAPOD. Once potential subjects are identified, they will be approached by a study team member or the study coordinator at Prentice Hospital or at their first postpartum visit.*

17.2 *The source of our subjects will be women that have sustained OASIS after their first delivery within Prentice Women's Hospital.*

17.3 *Participants in this study will receive free parking vouchers for their follow up visits (2 visits). They will be able to keep the stimulation device at the end of the trial.*

18.0 Local Number of Subjects

18.1 *Assuming a 25% dropout rate, we will ultimately recruit 100 women (50 to each arm).*

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 *To protect privacy interests, the personal health information collected for research purposes will be collected from the subject's electronic medical record to limit the amount of people they interact with and provide personal information to.*

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19.2 *All interviews will be conducted in a private office or examination room to ensure confidentiality. Phone conversations will be conducted from private offices. Any study correspondence with patients will not indicate disease status or focus on the envelope. All physical exams will be conducted in a private examination room. Subjects will be allowed to skip any question on a questionnaire that makes them feel uncomfortable.*

19.3 *The study staff, including investigators and the study coordinator, will have access to the subject's medical record and study documents. All study documents will be kept in a locked cabinet and only those with password required access to EPIC will be able to access the subject's electronic medical record.*

19.4 *The study team will be permitted to access the subject's electronic medical record to access information about the subject.*

20.0 Economic Burden to Subjects

20.1 *Describe any costs that subjects may be responsible for because of participation in the research. There will be no costs associated with participation in this study.*

21.0 Consent Process

21.1 *Consent will be obtained from the patient by research staff, either by the study coordinator or by one of the investigators. The informed consent process is expected to take up to 30 minutes. The person obtaining consent will verbally go through the form and also allow time for the subject to read the form in its entirety. The subject will be allowed to consult with family. The person obtaining consent will ensure the subject understands the purpose and procedures of the study. After all the subject's questions have been answered, the subject will be given time to make a decision about enrollment. The original signed written consent form will be kept separately from research data, a signed copy will be sent to medical records, and a signed copy will be given to the patient. We will not be enrolling Non-English speaking subjects. Decisionally-impaired subjects will not be enrolled in our study.*

22.0 Process to Document Consent in Writing

22.1 *We will be following "SOP: Written Documentation of Consent (HRP-091)" and will be documenting process of consent in writing.*

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